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SupraVit® VRS 2000 Vitrectomy System User's Manual

Medical Instrument Development Laboratories, Inc.

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May 1998

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Section 1 Introduction

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This document is the User's Manual for the Medical Instrument Development Laboratories (MID Labs) SupraVit VRS 2000 Vitrectomy System, which is comprised of the SupraVit Vitrectomy System and the VitMate™ Fragmentation System.

CAUTION

Read manual before connecting or using these instruments.

1.1 Introduction to the Manual

This manual is divided into nine sections.

The first section, **Introduction,** is divided into subsections, including an introduction to this manual and the conventions used in it, an overview of the SupraVit VRS 2000 Vitrectomy System and descriptions of the SupraVit and VitMate controls.

The second section, **SupraVit Setup**, describes the pre-operative setup and adjustment of the SupraVit. It includes information regarding Aspiration, Cutting, Scissors, Illumination and the Footpedal.

The third section, **VitMate Setup**, describes the pre-operative setup and adjustment of the VitMate, including information about Cautery, Ultrasound and Low Pressure Air.

The fourth section, **Adjustment During Operation**, describes the use and adjustment of both instruments during surgery.

The fifth section, **Troubleshooting,** contains charts of information to aid the user in diagnosing and resolving performance problems with the SupraVit VRS 2000 Vitrectomy System.

The sixth section, **Cleaning and Maintenance**, contains information relating to the maintenance of the instruments, cleaning and sterilization of the ultrasound handpiece, and fuse replacement.

The seventh section, **SupraVit Specifications**, describes the performance parameters that the SupraVit will meet under normal operating conditions.

The eighth section, **VitMate Specifications**, describes the performance parameters that the VitMate will meet under normal operating conditions.

The final section, **Warranty**, describes the warranty for the instruments and the procedures that you must follow to obtain service under that warranty.

1.2 Conventions Used in this Manual

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- ALL CAPITALS – This manual uses ALL CAPITALS to describe a switch, control, or display when that item is similarly labelled on the instrument (e.g., the VIT button).
- Initial Capitals – When a control is not labelled, or the reference is not clear, this manual will use initial capitals when referring to that control (e.g., Illuminator Connector Bezels). Initial capitals are also used when referring to instrument status or operating modes (e.g., On, Off, or Pulsed).
- [ ] – Brackets [ ] are used to reference details in illustrations.
- Messages shown on the SupraVit Status Screen are shown in `this typeface` to distinguish them from surrounding text.
- Whenever a safety hazard exists, or can be created through the operation of the controls, a warning notice will appear before the action which can/will create the hazard. Such warnings will be printed in **BOLD** type and enclosed in a box. For example:

> ⚠ **WARNING**
>
> **Remove power cord from power entry module before replacing fuse.**

1.3 Introduction To The SupraVit VRS 2000 Vitrectomy System

MID Labs believes the SupraVit VRS 2000 represents one of the finest applications of technology in ophthalmic surgical instrumentation.

> **CAUTION**
>
> **Federal (USA) law restricts this device to use or sale by or on order of a physician.**

Primary Use

The SupraVit VRS 2000 is intended primarily for use in pars plana vitrectomy procedures. The SupraVit is also designed for use in such other ophthalmic procedures as lensectomy and membranectomy. The SupraVit VRS 2000 provides comprehensive functional capabilities for vitrectomy, including:

- Cutting
- Aspiration
- Intraocular Scissors

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- Fragmentation
- Illumination
- Fluid/gas Exchange
- Cautery

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1.4 Introduction To The SupraVit

The SupraVit is intended to provide basic vitrectomy capabilities as a stand-alone instrument. It is also intended to operate in conjunction with the VitMate™ Fragmentation System to provide complete vitreoretinal surgical capabilities. As a stand-alone instrument, the SupraVit provides the functions of vitreous cutting, aspiration, fiber optic illumination, and intraocular scissors drive. With the VitMate attached, fragmentation and cautery capabilities are added and controlled through the SupraVit system. The VitMate also provides a low-pressure air supply for fluid/gas exchange.

The SupraVit features a memory which remembers the last setting of each control when the power is turned off. This allows for rapid return to frequently used instrument settings.

1.4.1 SupraVit Front Panel

[1] MAIN POWER switch
Pressing the upper portion of this switch applies power to the instrument. Pressing the lower portion of this switch removes power from the instrument. The "0" indicates the off side of the switch and the "1" indicates the on side of the switch.

Immediately upon application of power, the internal electronics perform a series of self-tests. These tests include checking the functionality of each subsystem, the displays, and the audio tone generator. When the instrument has completed the self-test sequence, the Status Screen [13] shows the last settings that were used before the power was turned Off (or an error message may be displayed if corrective action is required).

[2] Primary Illuminator Connector Bezel
Rotation of the bezel controls On/Off and intensity of light source.

[3] Illuminator EJECT button
Pressing this button causes the illuminator drawer to spring open, allowing access for bulb replacement. If the illuminator is On when the EJECT button is pushed, the light source will automatically turn Off. Refer to Section 6.5 for more information about lamp replacement.

[4] Secondary Illuminator Connector Bezel
Rotation of the bezel controls On/Off and intensity of light source.

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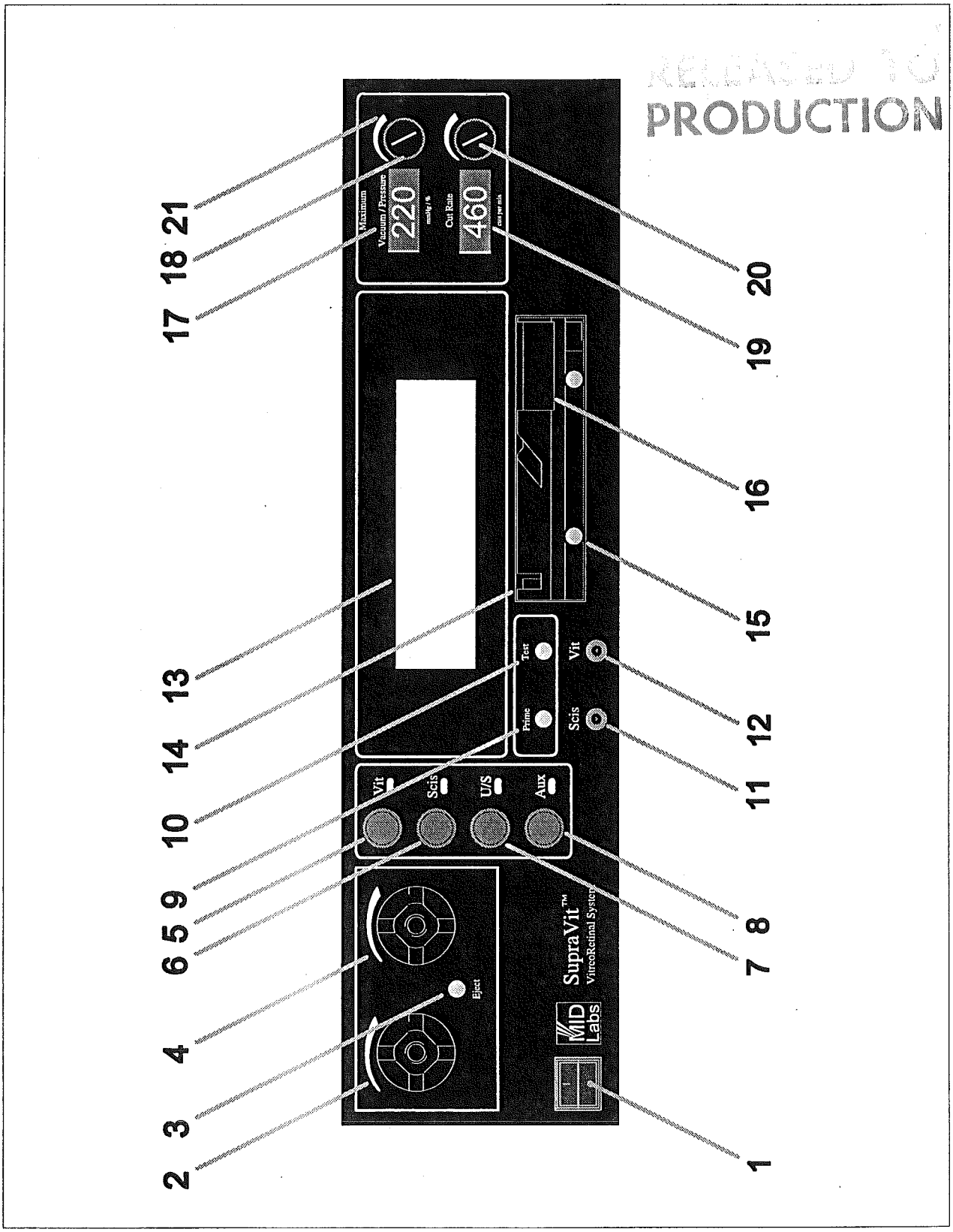

Figure 1-1
SupraVit Front Panel Controls, Indicators, and Connectors

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[5] VIT button and indicator

Pressing this button enables air flow to the VIT connector [12], and enables the Aspiration system. When the vitreous cutter drive is On, the indicator is illuminated and the Status Screen [13] displays

```
VIT CUTTER      OFF  vac   0
READY                mmHg
```

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or

```
VIT CUTTER      ON   vac   0
READY                mmHg
```

depending on the position of the footpedal.

Depressing the SupraVit Footpedal controls the aspiration vacuum at the vitreous cutter, and activates the cutter.

[6] SCIS button and indicator

Pressing this button enables air flow to the SCIS connector [11]. When the scissors drive is On, the indicator is illuminated and the Status Screen [13] displays

```
SCIS       PROPORTIONAL
READY
```

or

```
SCIS       PULSED
READY
```

depending upon the position of the foot plate toggle.

Swiveling the SupraVit Footpedal to the right and releasing it (toggle right) sets the Scissors mode to Pulsed. Swiveling the SupraVit Footpedal to the left and releasing it (toggle left) sets the Scissors mode to Proportional.

[7] U/S button and indicator

Pressing this button enables ultrasound at the VitMate™ Fragmentation System. When ultrasound is on, the indicator is illuminated and the Status Screen [13] displays

```
U/S              vac          0
READY            mmHg.
```

If U/S is turned On and the VitMate Fragmentation System is not connected, the instrument emits five high-frequency beeps, and the Status Screen [13] displays

```
VITMATE IS NOT CONNECTED
Connect VitMate for U/S
```

[8] AUX button and indicator

The AUX button gives the user access to various setup functions:

- Aspiration Audio signal enable/disable
- Cautery Control enable/disable

- Reflux Control enable/disable

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Each time the AUX button is pressed the next setup function is selected, and the Status Screen displays information relating to changing the setting for that function. Press the SCIS, VIT, or U/S button to exit from Setup mode.

[9] PRIME button

Pressing this button activates priming through the ASP connector [14]. The Status Screen [13] displays

```
PRIME
Put probe tip in sterile soln
Press PRIME to begin
```

Pressing the PRIME button again causes priming to begin. The Status Screen [13] displays

```
PRIMING
Press PRIME to end
```

Priming continues until the PRIME button is pressed again, or until 60 seconds has elapsed.

[10] TEST button

Pressing this button activates a self-test of the currently selected subsystem. For more information about the self-test sequences, please refer to Section 2, Setup.

[11] SCIS connector

This male luer-lock connector is the pneumatic drive output for the intraocular scissors.

[12] VIT connector

This male luer-lock connector is the pneumatic drive output for the vitreous cutter.

[13] Status Screen display

The Status Screen displays the status of the selected subsystem and shows actual values of aspiration vacuum in Vitrectomy and Ultrasound modes. The status screen is also used to display error messages.

[14] Aspiration connector

This is the slot where the female luer-lock connector is located once the collection set is installed.

[15] Aspiration Collection Bag hanging studs

These studs (the one indicated, and the one to its right) are used to hang the collection bag on the aspiration drawer.

[16] Aspiration Drawer handle

Pulling this handle will release the Aspiration Drawer, allowing it to slide open. The instrument emits five high-frequency beeps, and the Status Screen [13] displays

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```
ASPIRATION DRAWER IS OPEN
Load tube set and close drawer
```

whenever the drawer is open. Upon closing the drawer, the Status Screen displays

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```
Aspiration test required
Please wait
```

until the Aspiration Test is completed.

[17] MAXIMUM VACUUM / PRESSURE display

When the instrument is in Vitrectomy mode, this three digit display shows the maximum vacuum setting for the aspiration system in mmHg. Aspiration vacuum is adjusted with the MAXIMUM VACUUM / PRESSURE control [18]. When the instrument is in Scissors mode, this three digit display shows the maximum pressure setting for the scissors drive as a percentage of 40 p.s.i.

[18] MAXIMUM VACUUM / PRESSURE control

When the instrument is in Vitrectomy mode, this control sets the maximum aspiration vacuum (in 5 mmHg increments between 0 and 100 mmHg, then in 10 mmHg increments to a maximum of 500 mmHg). When the instrument is in Scissors mode, this control sets the maximum scissors drive pressure (in 5% increments between 0 and 100%).

The control rotates freely beyond the indicated limits.

[19] CUT RATE display

When the instrument is in Vitrectomy mode, this three digit display shows the cut rate of the vitrectomy cutter in cuts per minute (cpm), as adjusted by the CUT RATE control [20].

When the instrument is in Pulsed Scissors mode, this display shows the maximum cut rate of the intraocular scissors in cpm, as adjusted by the CUT RATE control [20].

[20] CUT RATE control

When the instrument is in Vitrectomy mode, this control adjusts the cut rate of the vitrectomy cutter (in increments of 10, between 60 and 800 cpm).

In Pulsed Scissors mode, this control adjusts the maximum cut rate of the intraocular scissors (in increments of 10, between 60 and 200 cpm).

The control rotates freely beyond the indicated limits.

[21] Intensity Symbol

This symbol shows the direction for increasing or decreasing the control settings. The large side of the symbol indicates the direction to rotate the control to increase the setting, and the small side of the symbol indicates the direction to rotate the control to decrease the setting.

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1.4.2 SupraVit Rear Panel

Numbers in brackets [ ] refer to Figure 1-2 on the next page.

[1] Power Entry Module
The supplied power cord connects between this connector and the AC supply receptacle. Grounding reliability can only be assured when the instrument is connected to an equivalent receptacle marked "Hospital Grade."

[2] Air Input
The supplied pneumatic hose connects between this connector and the air supply connector. The instrument requires clean dry air, or nitrogen, at a pressure between 60–120 psi.

[3] Fuse
Refer to Section 6.3 for fuse replacement information.

[4] FOOTPEDAL receptacle
The SupraVit Footpedal connects to this receptacle. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

[5] VITMATE receptacle
The supplied cable connects between this receptacle and the receptacle marked "VITRECTOMY SYSTEM" on the rear panel of the VitMate™. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

[6] VOLUME CONTROL
This control adjusts the volume of the audio tones emitted by the SupraVit. The control adjusts the volume of all tones; they are not individually adjustable. Turn the control clockwise to increase the volume.

[7] Console Identification Label
This label identifies product name, model number, serial number, date of manufacture and Underwriters Laboratories listing mark and number.

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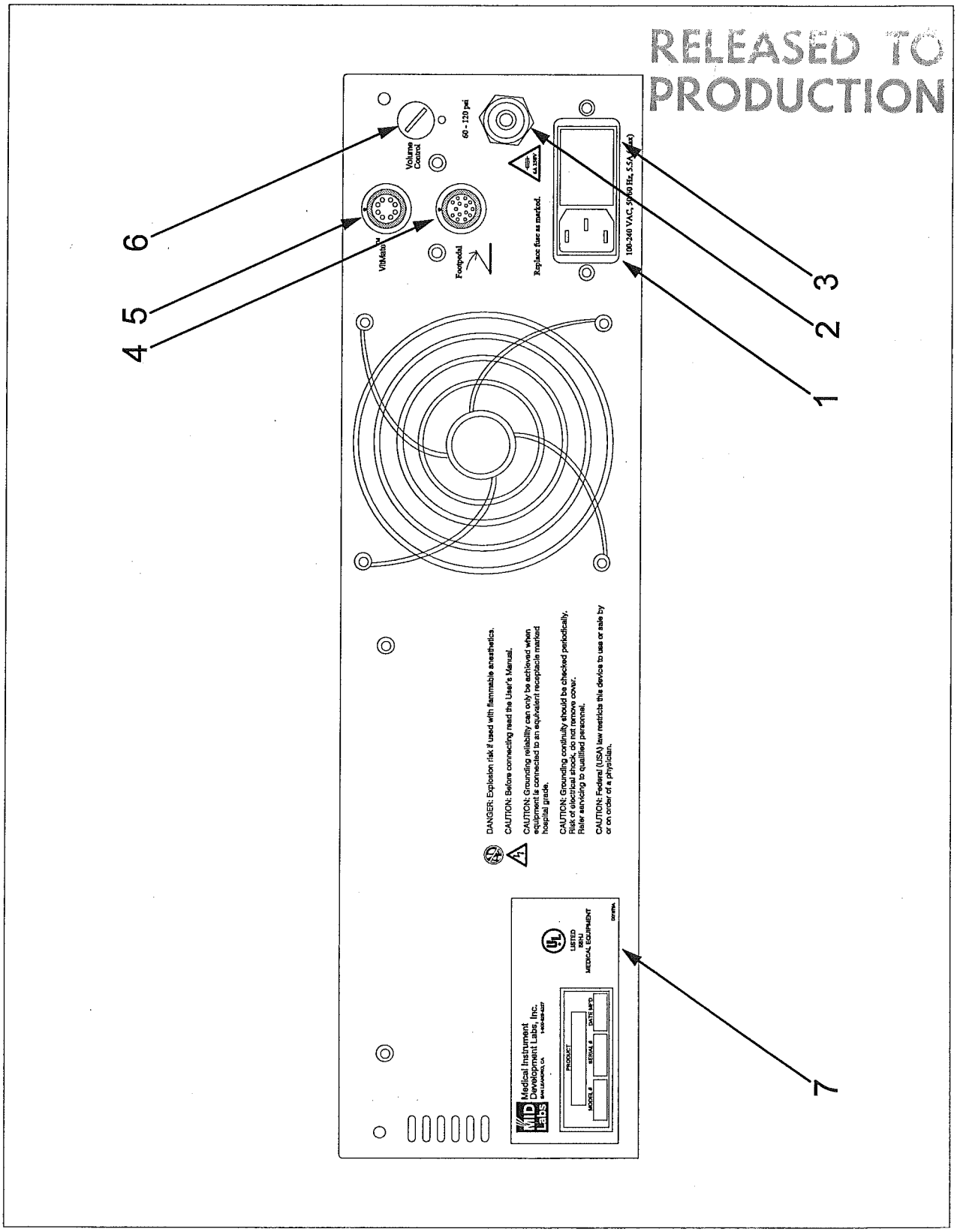
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Volume Control
60 - 120 psi
VitMatic
Footpedal
Replace fuse as marked.
100-240 VAC, 50/60 Hz, 5.5A (Max)
DANGER: Explosion risk if used with flammable anesthetics.
CAUTION: Before connecting read the User's Manual.
CAUTION: Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked hospital grade.
CAUTION: Grounding continuity should be checked periodically. Risk of electrical shock, do not remove cover. Refer servicing to qualified personnel.
CAUTION: Federal (USA) law restricts this device to use or sale by or on order of a physician.
Medical Instrument Development Labs, Inc.
MEDICAL EQUIPMENT
PRODUCT
MODEL #
SERIAL #
DATE MFD
1
2
3
4
5
6
7

Figure 1-2
SupraVit Rear Panel Controls and Receptacles

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1.4.3 SupraVit Footpedal

The SupraVit responds to vertical (compression) and lateral (swivel) motions of the Footpedal. Vertical motion is accomplished through the treadle [2], and lateral motion through the footplate [1]. The current mode dictates how the SupraVit responds to these motions.

Footpedal Control in VIT Mode

Swivel the footplate to the right and release it to enable the vitrectomy probe cutter; swivel the footplate to the left and release it to disable the cutter.

Depress the treadle to activate aspiration. Aspiration vacuum will increase linearly with the treadle position up to the preset maximum on the MAXIMUM VACUUM/PRESSURE display.

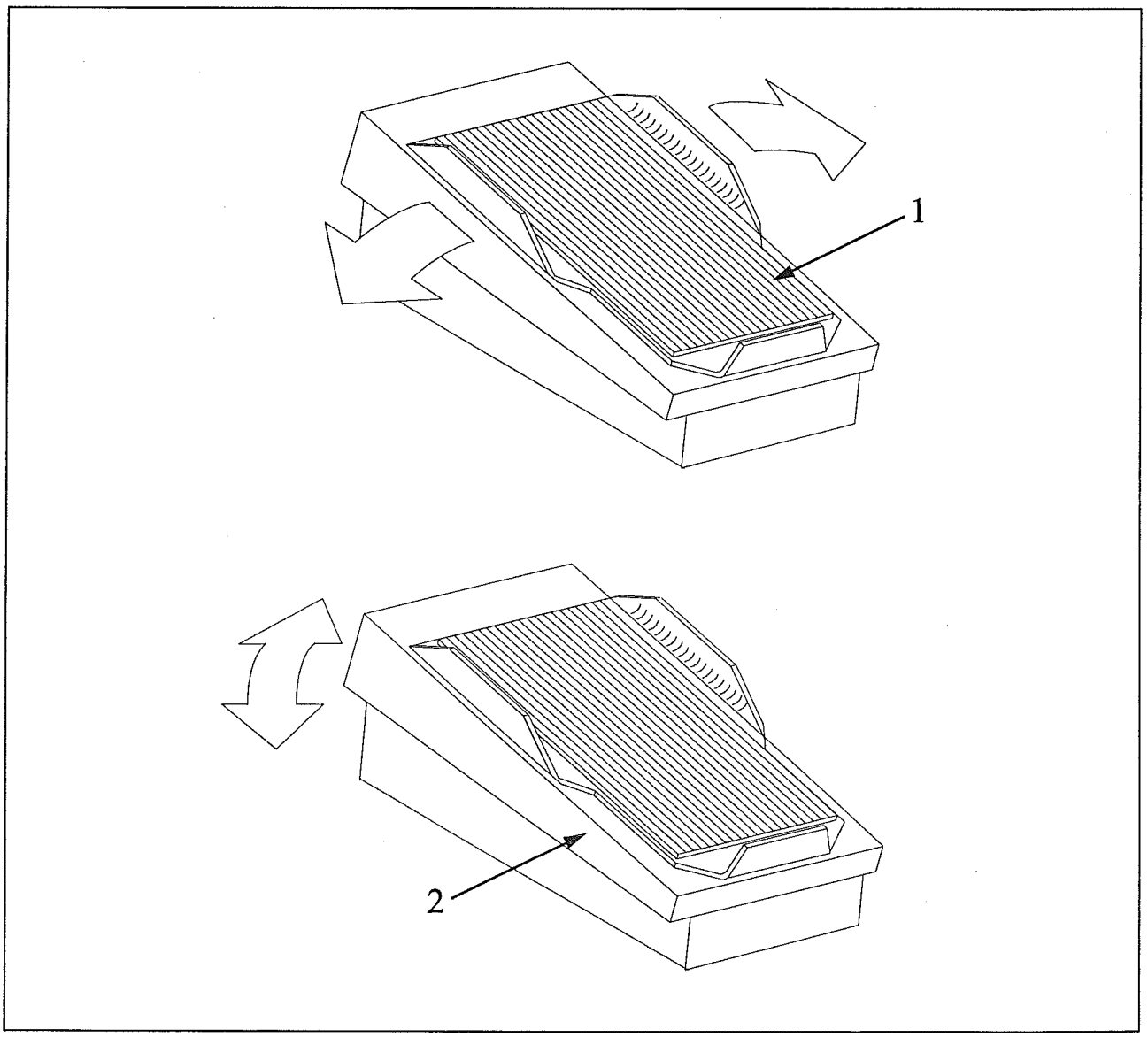

Figure 1-3
SupraVit Footpedal

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To activate cautery, (if enabled) first swivel the footplate to the left. While continuing to hold it left, depress the treadle. Release the footpedal to deactivate cautery.

To activate reflux, (if enabled) first swivel the footplate to the right. While continuing to hold it right, depress the treadle. Release the footpedal to deactivate reflux.

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Footpedal Control in SCIS Mode

Swivel the foot plate to the right and release it to enable pulsed scissors cutting. Swivel the foot plate to the left and release it to enable proportional scissors cutting.

When in pulsed mode, depress the treadle to activate cutting. The position of the treadle controls the cut rate from 60 cpm to the selected maximum. When in proportional mode, use the treadle to control the position of the scissors blades. Fully depress the treadle to close the scissors blades completely.

To activate cautery, (if enabled) first swivel the footplate to the left. While continuing to hold it left, depress the treadle. Release the footpedal to deactivate cautery.

Footpedal Control in U/S Mode

Depress the treadle to activate aspiration. Aspiration vacuum will increase linearly with the treadle position up to the preset maximum on the MAXIMUM VACUUM/PRESSURE display. While depressing the treadle, swivel the footplate to the right and hold it to activate U/S power. Center the footplate to deactivate U/S power.

To activate cautery, (if enabled) first swivel the footplate to the left. While continuing to hold it left, depress the treadle. Release the footpedal to deactivate cautery.

To activate reflux, (if enabled) first swivel the footplate to the right. While continuing to hold it right, depress the treadle. Release the footpedal to deactivate reflux.

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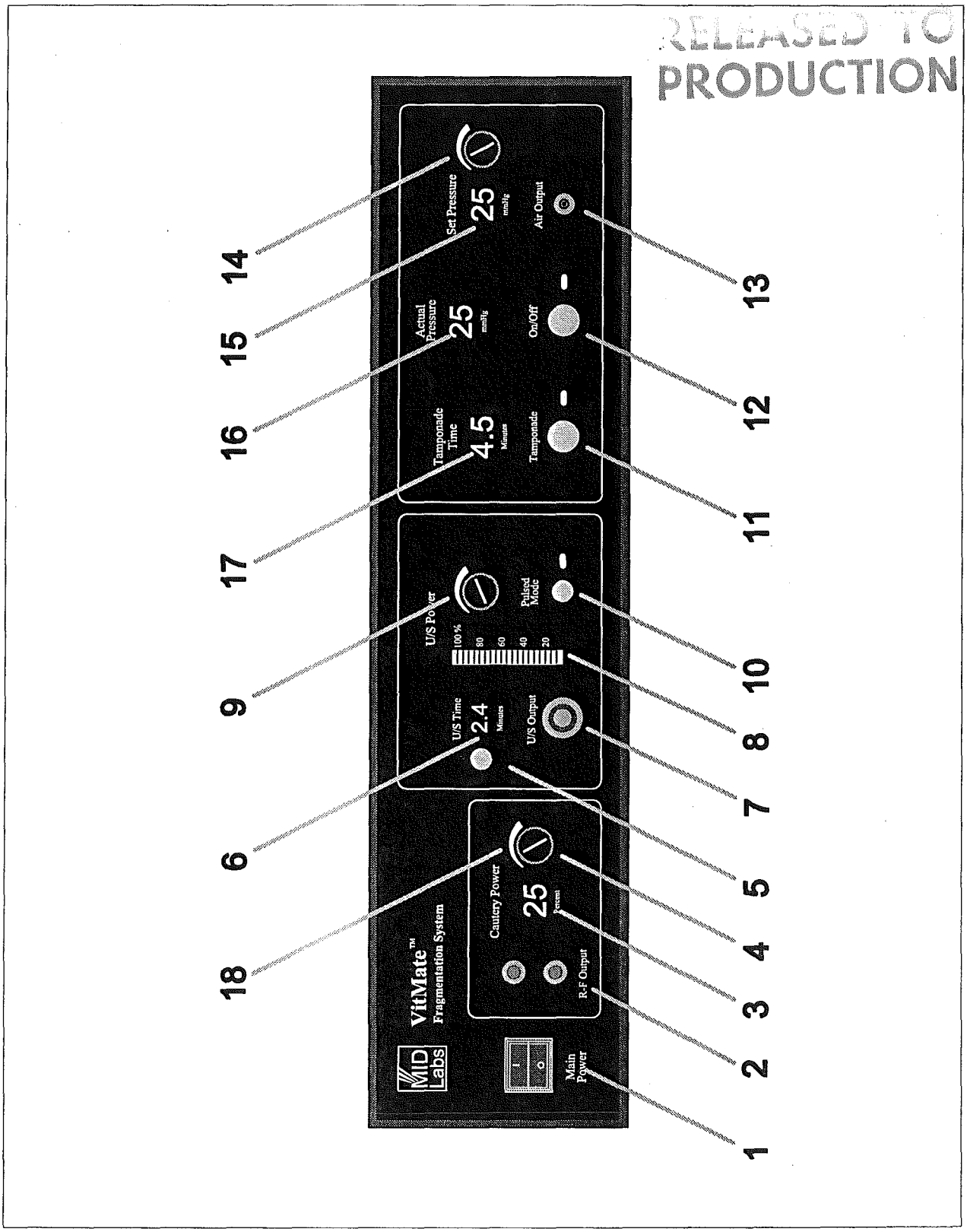

Figure 1-4
VitMate™ Front Panel Controls, Indicators, and Connectors

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1.5 Introduction To The VitMate™

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The VitMate Fragmentation System is intended to supplement the functionality of the SupraVit system. When used in conjunction with the SupraVit, the VitMate provides R-F power for cautery, high-performance ultrasound for fragmentation, and a precise, adjustable, low-pressure air supply with pre-settable tamponade. Ultrasound output is activated by the SupraVit footpedal. R-F power is activated by either the SupraVit or the VitMate footpedal. The low pressure air supply and tamponade are controlled from the front panel of the VitMate instrument.

The VitMate features a memory which remembers the last setting of each control when the power is turned off. This allows for rapid return to frequently used instrument settings.

The VitMate Fragmentation System is also intended to supplement the functionality of the following vitrectomy systems: MID Labs MVS®XII and MVS®XX, the Storz MicroVit® and the Alcon® MVS®XII and MVS®XX.

1.5.1 VitMate Front Panel

Numbers in brackets [ ] refer to Figure 1-4

[1] MAIN POWER switch

Pressing the upper portion of this switch applies power to the instrument. Pressing the lower portion of this switch removes power from the instrument. The "0" indicates the off side of the switch and the "1" indicates the on side of the switch.

Immediately upon application of power, the internal electronics perform a series of self-tests. These tests include checking the functionality of each subsystem, the displays, and the audio tone generator. When the instrument has completed the self-test sequence, the displays and indicators on the front panel will show the last settings that were used before the power was turned off. If at the end of the self-test sequence, the displays are flashing or "Er" is displayed, refer to Section 5, Troubleshooting.

[2] R-F OUTPUT receptacles (banana jacks)

These industry-standard banana-jack R-F OUTPUT receptacles can be used with all banana-plug type coagulation handpiece cables. The amplitude modulated R-F power output is bipolar and floating from ground.

[3] CAUTERY POWER PERCENT display

This two-digit display shows the current setting of the CAUTERY POWER control in 5% increments between 0 and 99%.

If an error condition in the cautery circuitry is detected during the power-on self-test, this display will show "Er." If neither the VitMate™ or SupraVit footpedals are connected, this

display will show "CF" (Connect Footpedal). If either of these error codes occur, refer to Section 5, Troubleshooting.

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[4] **CAUTERY POWER control**
This control adjusts the amount of power available at the R-F OUTPUT receptacles when R-F power is activated. The control rotates freely beyond the indicated limits.

When the Cautery Power is active, the instrument emits a continuous high-frequency tone. The volume level of this tone is adjustable using the VOLUME CONTROL on the back panel.

[5] **Ultrasound Time Reset button**
Pressing this button causes the U/S TIME display to be reset to zero. This display can be reset at any time, including while the ultrasound is activated.

[6] **U/S TIME display**
This two digit display shows, in minutes and tenths, the total amount of time that ultrasound power has been active since the last time the display was reset.

If the handpiece is not connected to the U/S OUTPUT connector, this display will be blank. If the VitMate Fragmentation System is not connected to the SupraVit, this display will show "CC" (Connect Cable). If there is an error condition in the Handpiece protection circuit, ultrasound power output will be cut off and this display will show "HF" (Handpiece Fault). If any of these errors occur, refer to Section 5, Troubleshooting.

[7] **U/S OUTPUT receptacle**
This receptacle provides ultrasound power and ground protection to the VitMate fragmentation handpiece. When connecting the handpiece, align the red dot on the plug with the red dot on the U/S OUTPUT receptacle, and push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

[8] **U/S POWER bar-graph display**
When ultrasound is not activated, the bar-graph displays the current setting of the U/S POWER control by illuminating one bar segment. When ultrasound is activated by the SupraVit or another vitrectomy system footpedal, the remaining bar-graph segments below the segment indicating the set power level become illuminated, and the instrument emits a continuous low frequency tone.

[9] **U/S POWER control**

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[9] U/S POWER control

This control adjusts the intensity of the ultrasound power delivered to the fragmentation handpiece when ultrasound is activated by the vitrectomy system footpedal. Ultrasound power is adjustable in 5% increments between 10 and 100%. The control rotates freely beyond the indicated limits.

[10] PULSED MODE button and indicator

Pressing this button alternately turns Pulsed mode On and Off. When the indicator is illuminated, ultrasound power will be pulsed at 10 pulses per second when activated by the SupraVit Footpedal. When the indicator is Off, ultrasound power will be delivered continuously when activated by the SupraVit Footpedal.

[11] TAMPONADE button and indicator

Pressing this button, when air flow is On, alternately turns Tamponade On and Off. When Tamponade is turned On, the indicator is illuminated, and the pressure of the Low Pressure Air System increases from the Set Pressure to the Tamponade Pressure. Tamponade is turned Off when the TAMPONADE button is pressed again. When Tamponade is first activated, the instrument emits two mid-frequency beeps. When Tamponade is deactivated, the instrument emits one beep.

Holding this button pressed, when air flow is Off, blanks the ACTUAL PRESSURE display and shows the Tamponade Pressure setting on the SET PRESSURE display.

[12] ON/OFF button and indicator

Pressing this button, alternately turns On and Off the flow of the air through the AIR OUTPUT connector [13] at the pressure set by the SET PRESSURE control [14]. When air flow is On, the indicator is illuminated. Pressing this button when Tamponade is On will turn Tamponade Off.

[13] AIR OUTPUT connector

The male luer-lock connector is the air output connector from the Low Pressure Air System.

[14] SET PRESSURE control

This control adjusts the pressure setting of the Low Pressure Air System in 1 mmHg increments between 0 and 99 mmHg.

In addition, when air flow is Off, and the TAMPONADE button is held pressed, this control adjusts the Tamponade Pressure.

Also, when air flow is On, and Tamponade is activated, this control adjusts the Tamponade Pressure.

The control rotates freely beyond the indicated limits.

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[15] SET PRESSURE display

This two digit display shows the pressure setting of the Low Pressure Air System, in mmHg, as adjusted by the SET PRESSURE control [14]. The display flashes and the mid-frequency beep is emitted once every six seconds anytime the Set Pressure is equal to or greater than 50 mmHg and the air flow is On.

When air flow is Off, and the TAMPONADE button is held pressed, this display shows the Tamponade Pressure setting.

[16] ACTUAL PRESSURE display

This two-digit display shows the Actual Pressure, in mmHg of air delivered by the Low Pressure Air System. If the Actual Pressure differs from the Set Pressure by more than 5 mmHg for more than two seconds, the display flashes and the instrument emits a mid-frequency beep twice each second.

[17] TAMPONADE TIME display

This two-digit display shows the Tamponade time in minutes and tenths of a minute. When Tamponade is not active, the display is blank. When Tamponade is active, this display counts up and shows the running time for that Tamponade session.

[18] Intensity Symbol

This symbol shows the direction for increasing or decreasing the control settings. The large side of the symbol indicates the direction to rotate the control to increase the setting, and the small side of the symbol indicates the direction to rotate the control to decrease the setting.

1.5.2 VitMate™ Rear Panel

Numbers in brackets [ ] refer to Figure 1-5 on the next page.

[1] Power Entry Module

The supplied power cord connects between this connector and the AC supply receptacle. Grounding reliability can only be assured when the instrument is connected to an equivalent receptacle marked "Hospital Grade."

[2] FUSE

Refer to Section 6.3 for fuse replacement information.

[3] VOLUME CONTROL

This control adjusts the volume of the audio tones emitted by the Cautery, Ultrasound, and Low Pressure Air Systems. The control adjusts the volume of all tones; they are not individually adjustable. Turn the control clockwise to increase the volume.

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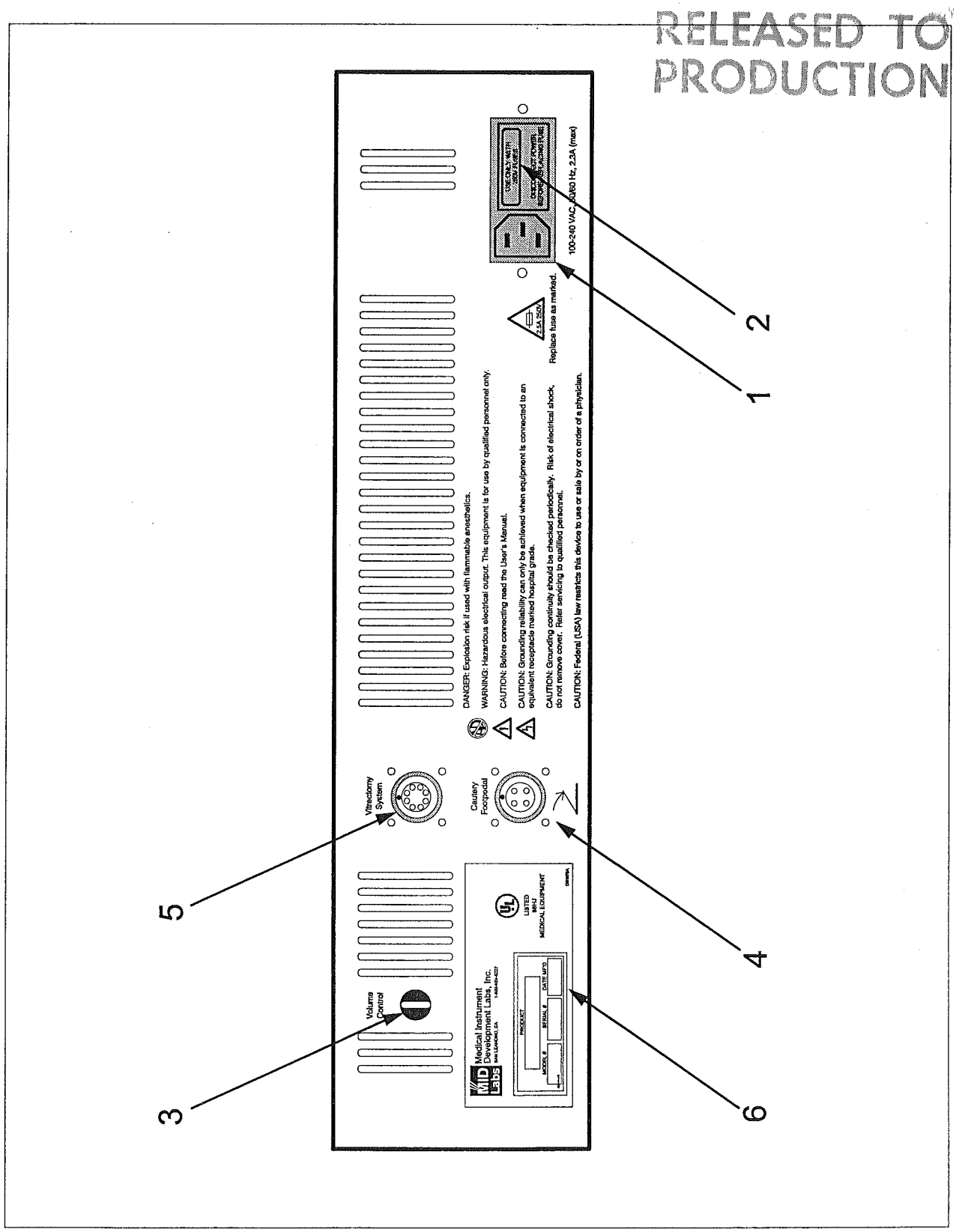
1
2
3
4
5
6
Vitrectomy System
Cautery Footpodal
Volume Control
Medical Instrument Development Labs, Inc.
DANGER: Explosion risk if used with flammable anesthetics.
WARNING: Hazardous electrical output. This equipment is for use by qualified personnel only.
CAUTION: Before connecting read the User's Manual.
CAUTION: Grounding reliability can only be achieved when equipment is connected to an equivalent receptacle marked hospital grade.
CAUTION: Grounding continuity should be checked periodically. Risk of electrical shock, do not remove cover. Refer servicing to qualified personnel.
CAUTION: Federal (USA) law restricts this device to use or sale by or on order of a physician.
Replace fuse as marked.
100-240 VAC, 50/60 Hz, 2.2A (max)

Figure 1-5
VitMate™ Rear Panel Controls and Receptacles

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[4] CAUTERY FOOTPEDAL receptacle
The supplied Cautery Footpedal connects to this receptacle. Cautery can be controlled using either the SupraVit Footpedal, or the VitMate™ Cautery Footpedal. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

[5] VITRECTOMY SYSTEM receptacle
The cable supplied with the SupraVit connects between this receptacle and the receptacle marked "VITMATE" on the rear panel of the SupraVit. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

[6] Console Identification Label
This label identifies product name, model number, serial number, date of manufacture and Underwriters Laboratories listing mark and number.

1.5.3 VitMate Cautery Footpedal

Depressing the VitMate Cautery Footpedal activates cautery power at the level shown on the CAUTERY POWER PERCENT display. Cautery power can also be activated by the SupraVit Footpedal.

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Section 2 SupraVit Setup

This section describes the pre-operative setup and adjustment of the SupraVit Vitrectomy System.

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CAUTION

Setup should be performed with all SupraVit accessories removed from patient field.

2.1 General

2.1.1 Placement

Place the VitMate™ on top of the SupraVit. If not possible, place it on one side of the SupraVit. The base of the SupraVit should be at least 3" above the patient eye level. It is recommended that both the SupraVit and the VitMate be located at least 6" from any other electrical devices.

Note: *Instrumentation capable of causing electromagnetic interference with the SupraVit may be present in hospital environments. Because MID Labs cannot predict all conditions in which the SupraVit will be used, the following considerations are recommended:*

Maintain a physical separation of at least six inches between other electrically powered devices and the SupraVit and VitMate instruments. This separation includes power cords and cables.

If possible, plug the SupraVit and VitMate into an isolated circuit.

Pay special attention to known sources of electromagnetic interference such as cellular phones. Consult your biomedical engineering department for further information and aid in identifying these sources.

2.1.2 Connecting the SupraVit Footpedal

Follow these steps to connect the SupraVit Footpedal:

1. Plug the SupraVit Footpedal connector into the SupraVit rear panel receptacle marked "FOOTPEDAL."
2. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

2.1.3 Connecting to Electrical Power

With the front panel MAIN POWER switch in the Off position, connect the supplied power cord between the Power Entry Module on the rear panel of the instrument and an AC power receptacle isolated from other electrical devices. The SupraVit will automatically adjust to input power in the range of 100–240 VAC, 50 or 60 Hz.

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2.1.4 Connecting to Pneumatic Power

With the front panel MAIN POWER switch in the Off position, connect the supplied air hose between the Air Input on the rear panel and a source of clean, dry air or nitrogen at 60–120 psi. The air hose should not be pressurized when connecting to the SupraVit. Push straight in until the plug "clicks" into place.

2.1.5 Connecting to the VitMate™ Fragmentation System

Follow these steps to connect the SupraVit to the VitMate Fragmentation System.

1. Plug the connector of the interconnect cable supplied with the SupraVit into the rear receptacle marked "VITMATE".
2. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.
3. Plug the other end of the cable into the receptacle marked "VITRECTOMY SYSTEM" on the rear panel of the VitMate.
4. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

2.2 Aspiration

2.2.1 Introduction

The SupraVit Vitrectomy System provides linear aspiration controlled by the footpedal. The maximum vacuum level is adjustable within the range of 0–500 mmHg, and is preset on the SupraVit console.

2.2.2 Installing the SupraBag® Collection Set

NOTE: *Numbers in square brackets refer to Figure 2-1.*

Follow these steps to install the SupraBag Collection Set:

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1. Attach the SupraBag Collection Set to the SupraVit by placing the holes at the top of the bag over the mounting studs [1] on the aspiration drawer. Be sure the tubing exits from the top left of the bag.

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CAUTION

Place SupraVit instrument so that the SupraBag hangs freely from the aspiration drawer studs. The bag must not be bent, folded or constricted in any manner.

2. With the SupraVit turned on, open the aspiration drawer by pulling out on the handle [2]. The drawer will release and slide open.

3. Slip the clear section of tubing at the top of the SupraBag Collection Set into the angled slot [3] leading into the aspiration drawer.

4. Press the check valve into the relieved section [4] of the tubing slot.

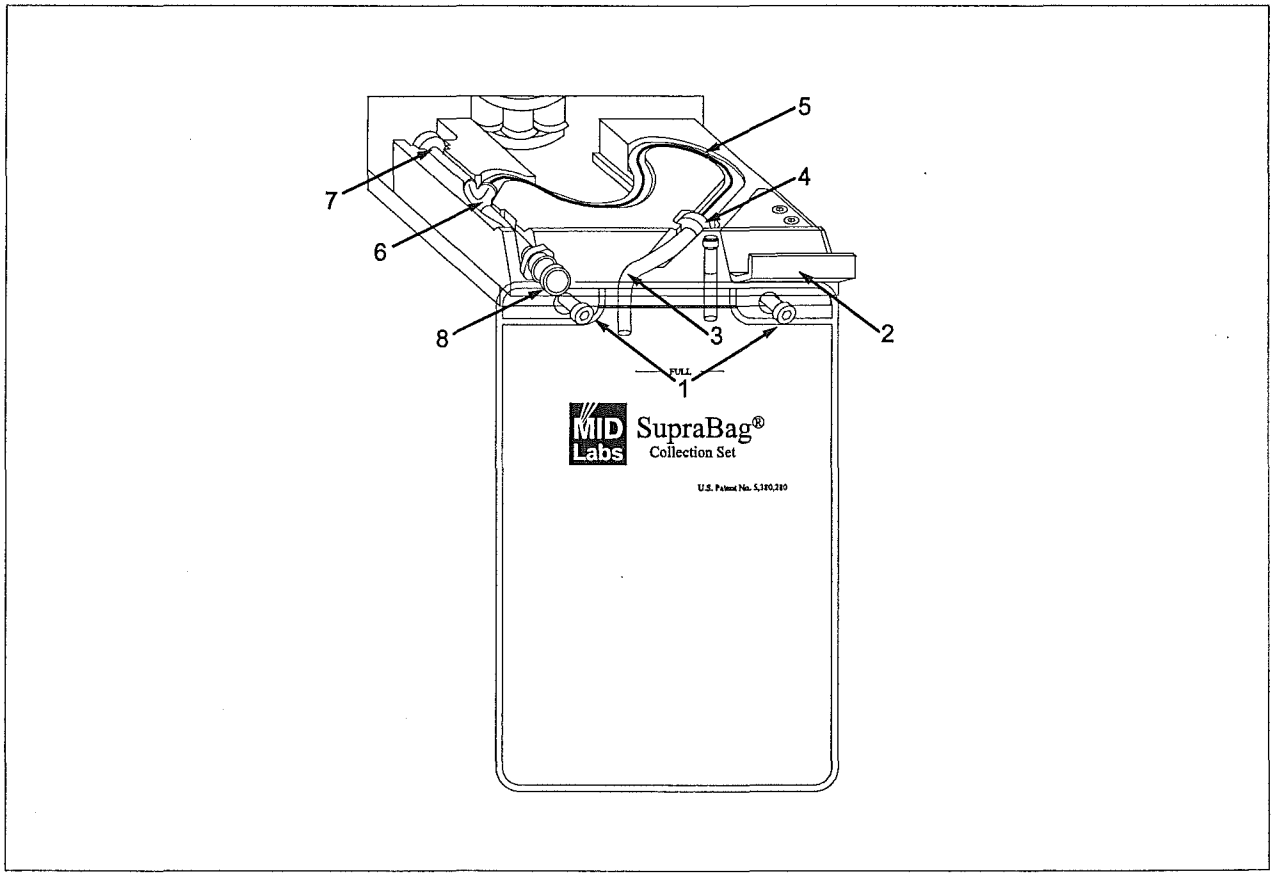

Figure 2-1

SupraVit Aspiration Drawer

5. Continue to press the tubing firmly into the slot [5], taking care to prevent twisting.

6. Press the 'Y' tubing section firmly into the 'Y' section [6] of the aspiration drawer slot. Move slightly to the right and press the tubing down so that the tube is firmly in the slot. Check that the tubing loop follows the curve of the aspiration drawer roller interface.

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7. Press the rear check valve firmly into the relieved slot [7].

8. Press the luer fitting into the front slot [8] of the aspiration drawer. Work your thumb back along the tubing to make sure the tubing, the 'Y,' and the rear check valve are firmly fitted into the slot.

9. Check that the tubing is not kinked or twisted before pushing the drawer closed.

NOTE: *When removing the SupraBag® Collection Set leave the Vitreous Cutter tubing set connected. This will prevent any possibility of fluid escaping when extracting the SupraBag Collection Set tubing from the aspiration drawer.*

2.2.3 Testing the Aspiration System

After the SupraBag Collection Set is installed and the drawer is closed, the Aspiration system self-test proceeds automatically. The Status Screen displays

```
Aspiration test required
Please wait
```

until testing is complete.

If there is a problem with the aspiration system, such as a kinked tube, the Status Screen displays a message indicating the nature of the problem. The possible messages are:

```
UNABLE TO ACHIEVE VACUUM
UNABLE TO CONTROL VACUUM
VACUUM TRANSDUCER DISCREPANCY
EXTERNAL LEAK DETECTED
UNABLE TO RELIEVE VACUUM
FOOTPEDAL INTERLOCK FAILURE
```

Open the drawer and inspect the collection set. Follow Section 2.2.2 to reinstall if necessary. Testing resumes automatically when the drawer is closed. If messages persist, refer to Section 5, Troubleshooting.

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2.3 Vitreous Cutter

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2.3.1 Introduction

The SupraVit System provides pneumatic drive for a guillotine-action vitreous cutter. The cut rate is adjustable from 60 to 800 cuts per minute (cpm) at the SupraVit front panel, while the footpedal provides on/off cutting control.

2.3.2 Connecting the Vitreous Cutter

Because actual practice and techniques vary depending upon location, it is assumed that all connections are made, and cutters are handled, using appropriate aseptic technique.

Follow these steps to connect the Vitreous Cutter to the SupraVit:

1. Press the MAIN POWER switch to turn On the instrument.
2. Connect the Vitreous Cutter tubing set female luer connector to the male luer-lock VIT connector on the SupraVit front panel.
3. Connect the Vitreous Cutter tubing set male luer connector to the female luer connector on the collection set at the front of the aspiration drawer.
4. Put the tip of the Vitreous Cutter in a container of sterile solution and press the PRIME button. The Status Screen displays

```
Put probe tip in sterile soln
Press PRIME to begin.
```

5. Press the PRIME button again to begin priming. The Status Screen displays

```
PRIMING
Press PRIME to end
```

until the PRIME button is pressed again or 60 seconds has elapsed. Confirm that all bubbles are removed.

6. Press the TEST button. The Status Screen displays

```
Put probe tip in sterile soln
Press TEST to begin.
```

Press the TEST button again to begin testing. The vitreous cutter operates at 600 cpm, and the Status Screen displays

```
Replace if bubbles are seen
Press TEST to end
```

until the TEST button is pressed to stop. Replace the probe if bubbles are observed at the tip of the needle.

7. Press the VIT button. The Status Screen displays

```
VIT CUTTER    OFF   vac   0
READY                     mmHg
```

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8. Adjust the CUT RATE control until the desired cut rate, in cpm, is shown on the CUT RATE display.

9. Adjust the MAXIMUM VACUUM / PRESSURE control on the front panel until the desired maximum aspiration vacuum is shown on the MAXIMUM VACUUM / PRESSURE display. The footpedal will linearly control the aspiration vacuum level between 0 mmHg and this maximum level.

2.4 Intraocular Scissors

2.4.1 Introduction

The SupraVit provides pneumatic drive for intraocular scissors. Scissors mode can be selected to be Proportional or Pulsed. Set to Proportional, the scissors are in a single-cut mode with the blade position proportional to the position of the footpedal (i.e., footpedal fully depressed equals scissor blades fully closed). Set to Pulsed mode, the pulse rate is determined by the position of the footpedal (i.e., footpedal fully depressed equals maximum preset pulse rate).

2.4.2 Connecting the Intraocular Scissors

Because actual practice and techniques vary depending upon location, it is assumed that all connections are made, and scissors are handled, using appropriate aseptic technique.

Follow these steps to connect the Intraocular Scissors:

1. Connect the scissors drive tubing set to the female luer SCIS connector on the front panel.

2. Press the SCIS button. The indicator becomes illuminated, and the Status Screen displays either

```
SCIS                PROPORTIONAL
READY
```

or

```
SCIS                PULSED
READY
```

depending upon the position of the Footpedal foot plate toggle.

3. Press the TEST button. The Status Screen displays

```
Scissors will open and close
Press TEST to begin
```


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Press the TEST button again to begin the test. The scissors will open and close at 60 cpm. Adjust the MAXIMUM VACUUM / PRESSURE control until the scissors blades close completely each time.

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Press the TEST button to end the test.

4. To change Scissors mode, swivel the foot plate to the right or left and release it. The Status Screen display changes to

```
SCIS                PULSED
READY
```

if Pulsed is selected (toggle right), or

```
SCIS                PROPORTIONAL
READY
```

if Proportional is selected (toggle left).

2.5 Illumination

2.5.1 Introduction

The SupraVit provides two illuminator receptacles for use with fiber optic light guides. The intensity of each illuminator is independently adjustable between 20% and 100% by turning the Illuminator Connector Bezel. The color temperature of the illumination is kept constant throughout the range by employing a mechanical dimmer instead of an electrical one. The lamps have "slow-start" circuitry to greatly extend their life, and a spare lamp is conveniently stored in the Illuminator Drawer. Refer to Section 6.5 for lamp replacement instructions.

2.5.2 Connecting a Fiber Optic Light Guide

Because actual practice and techniques vary depending upon location, it is assumed that all connections are made, and light guides are handled, using appropriate aseptic technique.

Follow these steps to connect a Fiber Optic Light Guide:

1. Insert the console end of the Fiber Optic Light Guide into the Primary Illuminator Connector Bezel until it is fully seated. See Fig. 1-1 [2].

2. Turn the Connector Bezel clockwise to turn On the illuminator lamp.

3. Continue to turn the Connector Bezel clockwise until the desired illumination level is reached.

4. A second Fiber Optic Light Guide can be connected to the Secondary Illuminator Connector Bezel [4] if desired.

2.6 Control of Aspiration Audio, Cautery and Reflux

2.6.1 Introduction

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The AUX button gives access to the following Setup mode functions:

- Aspiration Audio signal enable/disable
- Cautery Control enable/disable
- Reflux Control enable/disable

These control settings will be retained in memory when the SupraVit is turned off. They may be changed if desired. A tube set must be present in the aspiration drawer and the air hose must be connected in order to access the functions of the AUX button.

2.6.2 Selecting control options.

Follow these steps to select desired control settings:

With power on, push the AUX button until the Status Display reads "ASP AUDIO." Rotate the Maximum Vacuum/Pressure control to enable or disable Aspiration Audio. Selected status will show in the Status Display window.

Push the AUX button again. Rotate the Maximum Vacuum/Pressure control to enable or disable Cautery Control.

Push the AUX button again. Rotate the Maximum Vacuum/Pressure control to enable or disable Reflux Control.

Press the SCIS, VIT or U/S button to exit from the Setup mode.

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Section 3 VitMate Setup

This section describes the pre-operative setup and adjustments of the VitMate Fragmentation System when used in conjunction with the SupraVit.

CAUTION

Setup should be performed with all SupraVit and VitMate accessories removed from patient field.

3.1 General

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3.1.1 Placement

Place the VitMate on top of the SupraVit. If this is not possible, place it to one side of the SupraVit. It is recommended that both the SupraVit and the VitMate be located at least 6" from any other electrical device.

Note: *Instrumentation capable of causing electromagnetic interference with the VitMate may be present in hospital environments. Because MID Labs cannot predict all conditions in which the VitMate will be used, the following considerations are recommended:*

Maintain a physical separation of at least six inches between other electrically powered devices and the SupraVit and VitMate instruments. This separation includes power cords and cables.

If possible, plug the SupraVit and VitMate instruments into an isolated circuit.

Pay special attention to known sources of electromagnetic interference such as cellular phones. Consult your biomedical engineering department for further information and aid in identifying these sources.

3.1.2 Connecting the VitMate Cautery Footpedal

Cautery can be activated with either the VitMate Cautery Footpedal or the SupraVit Footpedal. If cautery activation through the VitMate Cautery Footpedal is desired, follow these steps:

1. Plug the VitMate Cautery Footpedal connector into the VitMate rear panel receptacle marked "CAUTERY FOOTPEDAL."

2. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

3.1.3 Connecting to Electrical Power

With the front panel MAIN POWER switch in the Off position, connect the supplied power cord between the Power Entry Module on the rear panel of the instrument and an AC power receptacle isolated from other electrical devices. The VitMate™ will automatically adjust to input power in the range of 100–240 VAC, 50 or 60 Hz.

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3.1.4 Connecting to the SupraVit

Follow these steps to connect the VitMate to the SupraVit.

1. Plug the 8-pin connector of the interconnect cable supplied with the SupraVit into the rear panel receptacle marked "VITRECTOMY SYSTEM" on the rear panel.
2. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.
3. Plug the other end of this cable into the "VITMATE" receptacle on the rear panel of the SupraVit.
4. Align the red dots on the plug and the receptacle. Push straight in until the plug "clicks" into place. To disconnect, grasp plug and pull straight out.

3.2 Setting Up the Cautery System

Follow these steps to connect the Cautery Handpiece to the VitMate.

1. Press the VitMate MAIN POWER switch to turn On the instrument.
2. Using appropriate aseptic technique, connect the banana plugs of the Cautery Handpiece to the front panel R-F OUTPUT receptacles.
3. Adjust the CAUTERY POWER control until the desired power level (in percent) is shown on the CAUTERY POWER PERCENT display.

3.3 Setting up the Ultrasound System

⚠ WARNING

Never operate the Handpiece with the Needle in air.

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Numbers in brackets [ ] refer to Figure 3-1.

Follow these steps to setup the VitMate for Ultrasound:

1. Press the MAIN POWER switch to turn On the instrument.
2. Using appropriate aseptic technique, attach the fragmentation needle to the handpiece and tighten securely with the needle wrench.
3. Connect the VitMate fragmentation handpiece plug to the front panel U/S OUTPUT receptacle. The U/S TIME display which was blank will now display "00". If an error code is displayed after attaching the handpiece, refer to Section 5, Troubleshooting.
4. Connect the 3-way stopcock [5] between the male [3] and female [4] luer connectors farthest away from the probe on the VIT probe aspiration line.

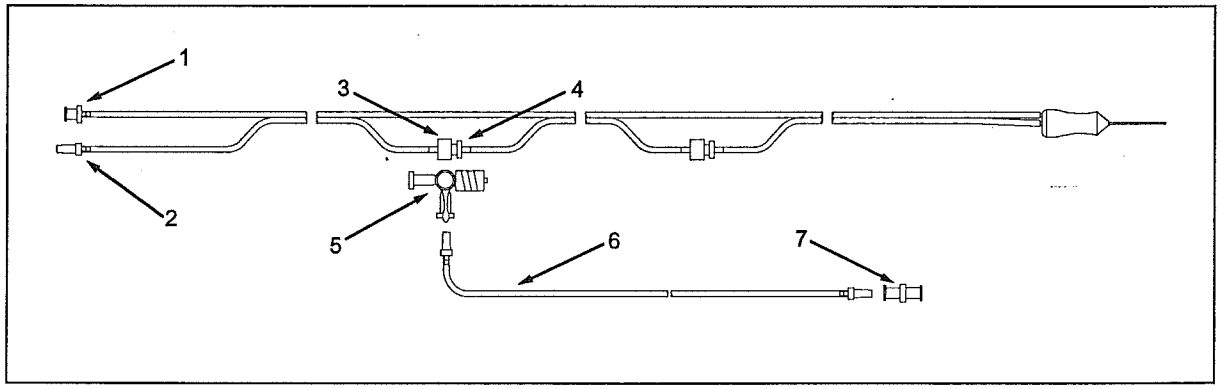

Figure 3-1

Aspiration Tubing Connection

NOTE: *The control lever on the three-way stopcock points toward the Off (blocked) tube. Therefore if the lever points toward the tube leading to the vitrectomy probe, aspiration through the probe is Off. If the lever points toward the tube leading to the fragmentation handpiece, aspiration through the handpiece is Off.*

If the lever points toward the aspiration tube leading to the SupraVit, all aspiration is Off. Never leave the lever in this position.

5. Install the extrusion tube set [6] into the side port of the stopcock [5].
6. Install the fragmentation handpiece onto the far end of the extrusion tube set using the coupler [7] if required. Turn the handle on the stopcock [5] toward the VIT probe handset.

7. Adjust the ultrasound power level by turning the U/S POWER control until the lighted bar-graph segment indicates the desired level.

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8. If the PULSED MODE indicator is illuminated, the VitMate™ is in Pulsed Ultrasound mode. If it is not illuminated, the VitMate is in Continuous Ultrasound mode. Press the PULSED MODE button to toggle between these two modes.

9. Set the SupraVit to Ultrasound mode by pressing the U/S button.

   NOTE: *Never operate the Handpiece with the needle in air.*

10. Prime the aspiration line by holding the fragmentation handpiece with the needle in a beaker of sterile solution and pressing the PRIME button on the SupraVit front panel.

    NOTE: *Do not allow the needle to come into contact with the glass of the beaker.*

11. Test the ultrasound output with the needle still in the beaker of sterile solution by pressing the TEST button on the SupraVit front panel. The bar-graph segments below the illuminated power level indicator become illuminated, the instrument emits a low-frequency tone, and cavitation at the handpiece tip will be observed. Press the TEST button again to end the test.

3.4 Setting up the Low Pressure Air System

Follow these steps to set up the Low Pressure Air system:

1. Press the MAIN POWER switch to turn on the instrument.

2. If air flow is On (indicator is illuminated), press the ON/OFF button to turn air flow Off.

3. Using appropriate aseptic technique, connect the filter of the air tubing set to the front panel luer-lock fitting labelled AIR OUTPUT.

4. Adjust the SET PRESSURE control until the SET PRESSURE display indicates the desired pressure.

5. Hold down the TAMPONADE button. Adjust the SET PRESSURE control until the desired Tamponade Pressure is shown on the SET PRESSURE display. Release the TAMPONADE button.

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Section 4 Adjustment During Operation

This section of the manual describes adjustments to the SupraVit and VitMate™ instruments during surgery.

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4.1 General

The volume of the audio tones emitted can be adjusted using the VOLUME CONTROL on the instrument's rear panel.

4.2 Aspiration

Aspiration is available only in Vitrectomy and Ultrasound modes.

- To increase or decrease the vacuum level, press down or release the SupraVit footpedal treadle. The aspiration vacuum will change in proportion to the position of the footpedal treadle from a minimum of 0 mmHg at the top of the treadle travel, to the maximum level set by the MAXIMUM VACUUM/PRESSURE control at the bottom of the treadle travel. The SupraVit Status Screen shows the actual vacuum level.
- To increase or decrease the maximum aspiration vacuum level, adjust the MAXIMUM VACUUM/PRESSURE control until the desired level is shown on the VACUUM/PRESSURE display. The maximum vacuum level can be adjusted between 0 and 500 mmHg in increments of 5 mmHg up to 100 mmHg, then in increments of 10 mmHg up to 500 mmHg. The control rotates freely beyond the indicated limits.

4.3 Cutting

The vitrectomy cutter is activated only in Vitrectomy mode.

- To increase or decrease the cut rate of the vitrectomy cutter, adjust the CUT RATE control until the desired cut rate in cuts per minute (cpm) is shown on the CUT RATE display. The cut rate can be adjusted between 60 and 800 cpm in increments of 10 cpm. The control rotates freely beyond the indicated limits.

4.4 Scissors

The intraocular scissors driver will operate the scissors in either of two modes, selected by the footpedal foot plate toggle.

- To select Proportional Scissors mode, press the SCIS button and then swivel the Footpedal foot plate to the left and release

it. In Proportional Scissors mode, the position of the scissors blade is directly proportional to the position of the Footpedal treadle. The Status Screen displays

```
SCIS            PROPORTIONAL
READY
```

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- To select Pulsed Scissors mode, press the SCIS button and then swivel the Footpedal foot plate to the right and release it. In Pulsed Scissors mode, the rate at which the scissors blades open and close is controlled by the Footpedal treadle. The Status Screen displays

```
SCIS            PULSED
READY
```

- To increase or decrease the maximum scissors pressure, adjust the MAXIMUM VACUUM/PRESSURE control until the desired maximum scissors pressure (in percent) is shown on the VACUUM/PRESSURE display. The pressure is adjustable between 0 and 100% of 40 psi in 1% increments. The control rotates freely beyond the indicated limits.

- To increase or decrease the maximum scissors cut rate in Pulsed Scissors mode, adjust the MAXIMUM CUT RATE control until the desired rate is shown on the CUT RATE display. The cut rate is adjustable between 60 and 200 cpm in 10 cpm increments. The control rotates freely beyond the indicated limits.

- To control the scissors cut rate, in Pulsed Scissors mode, depress or release the Footpedal treadle.

4.5 Illumination

Intraocular fiber optic illumination is available any time that power is applied to the SupraVit.

- Turn the Illuminator Connector Bezel clockwise to increase, or counter-clockwise to decrease the brightness of an illuminator. The illumination level is adjustable from 20% to 100%. Turning the Bezel fully counter-clockwise until it clicks turns Off that illuminator.

4.6 Cautery

Cautery functions are adjusted at the VitMate™ front panel, and are activated by either the SupraVit or the VitMate footpedal. When Cautery Power is active, the instrument emits a high-frequency tone.

- To activate cautery using the SupraVit Footpedal, hold the foot

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plate swiveled to the left and depress the treadle slightly, holding it as long as R-F power is required.

- To activate cautery using the VitMate™ Cautery Footpedal, depress the footpedal and hold as long as R-F power is required.
- To increase or decrease the R-F power output to the Cautery Handpiece, adjust the VitMate Cautery Power control until the desired power level is shown on the VitMate CAUTERY POWER PERCENT display. The power is adjustable in 5% increments from 0 to 99%. The control rotates freely beyond the indicated limits.

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4.7 Ultrasound System

Ultrasound functions are adjusted at the VitMate front panel and are available only when the SupraVit is in Ultrasound mode.

- To activate ultrasound power, press the U/S button on the SupraVit front panel and swivel the footpedal foot plate to the right, holding it as long as Ultrasound power is required. The footpedal treadle position controls the aspiration vacuum level.
- To increase or decrease the ultrasound power delivered to the VitMate Fragmentation Handpiece, adjust the VitMate U/S Power control until the desired power level is shown on the U/S POWER display. Ultrasound power is adjustable in 5% increments from 10% to 100%. The control rotates freely beyond the indicated limits.
- To change to or from Pulsed Mode ultrasound power, press the PULSED MODE button. The indicator is illuminated when the instrument is in Pulsed Mode.

4.8 Low Pressure Air System

Low Pressure Air System adjustments are made at the VitMate front panel.

- To turn the air flow On or Off, press the ON/OFF button. The indicator is illuminated when air flow is On.
- To increase or decrease the pressure of air delivered by the VitMate Low Pressure Air System, adjust the SET PRESSURE control on the VitMate front panel until the desired pressure, in mmHg, is shown on the SET PRESSURE display. The control rotates freely beyond the indicated limits.
- To turn Tamponade On or Off, press the TAMPONADE button. When Tamponade is On, the indicator is illuminated.

- To increase or decrease the pressure when Tamponade is On, adjust the SET PRESSURE control until the desired Tamponade Pressure is shown on the SET PRESSURE display. The instrument emits a mid-frequency beep once every six seconds whenever the Set Pressure is greater than 50 mmHg, and the air flow is On.

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Section 5 Troubleshooting

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This section of the manual contains information to aid the user in diagnosing performance problems with the SupraVit and VitMate™ instrument systems, and contains possible solutions to those problems. It is important when diagnosing a potential problem to make careful note of the settings, the exact message displayed on the status screen, and the numbers displayed on each of the numerical displays. Write this information down before turning off the power and call MID Labs Customer Support.

5.1 SupraVit Troubleshooting Guide

Condition	Cause	Correction
Status Display not illuminated.	Instrument not connected to AC power. Blown fuse. System malfunction.	Connect power cord from AC receptacle to Power Entry module on rear panel of the instrument. Replace fuse. Refer to Section 6.3, Fuse Replacement. Call MID Labs @ 1-800-929-5227
"PPI1 FAILURE" "PPI2 FAILURE" "PPI3 FAILURE" "LATCH FAILURE" "ANALOG SYSTEM FAILURE" "DISPLAY SYSTEM FAILURE" "SEC VACUUM XDCR OFFSET FAILURE" "SCISSORS VACUUM XDCR OFFSET FAILURE" "PRESSURE XDCR DISCREPANCY" "SCISSORS CONTROL FAILURE"	The appearance of any of these messages on the Status Screen during the Power On Self Test indicates a system malfunction.	Call MID Labs @ 1-800-929-5227
"PRESETS LOST. DEFAULTS USED"	Internal battery is dead.	Instrument will function but will use factory default settings. Battery is not user-replaceable. Call MID Labs @ 1-800-929-5227
"UNABLE TO CONTROL PRESSURE" shown on Status Screen.	Scissors not connected properly. System malfunction.	Check all tubing connections to scissors. Call MID Labs @ 1-800-929-5227

5.1 SupraVit Troubleshooting Guide, continued

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Condition	Cause	Correction
"VITMATE IS NOT CONNECTED" shown on Status Screen.	VitMate™ is not connected properly.	Connect cable between VitMate and SupraVit. Check that connectors are firmly seated.
"FOOTPEDAL IS NOT CONNECTED" shown on Status Screen.	Footpedal is not connected properly.	Connect footpedal. Check that connector is firmly seated.
"ASPIRATION DRAWER IS OPEN" shown on Status Screen.	Aspiration drawer is not fully closed.	Push drawer closed firmly. Check that the tubing is inserted correctly in the slot in the drawer.
"FOOTPEDAL IS DEPRESSED Release pedal to change mode" shown on Status Screen.	Button pressed to change modes while footpedal is depressed.	Release footpedal before pressing a button to change modes.
"ASPIRATION PINCH VALVE FAILURE" shown on Status Screen.	System malfunction.	Call MID Labs @ 1-800-929-5227
"VACUUM EXCEEDED CONTROL LIMITS" shown on Status Screen.	System malfunction.	Call MID Labs @ 1-800-929-5227
"VACUUM IS LOWER THAN REQUESTED" shown on Status Screen.	The aspiration vacuum level requested (through the treadle position and the setting of MAXIMUM VACUUM control) is not being maintained. Air leak in tubing between handpiece and console. SupraBag® is overfilled. SupraBag is folded or constricted. Foreign matter present on aspiration drawer rear seal.	This message may be shown briefly during some normal operating conditions. Look for bubbles in tubing, determine source of leak and correct. Replace SupraBag Collection Set. Place SupraVit instrument so that SupraBag hangs freely from drawer studs Clean the aspiration drawer rear seal per Section 6.6. If this message persists, call MID Labs @ 1-800-929-5227

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5.1 SupraVit Troubleshooting Guide, continued

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Condition	Cause	Correction
"LOW INPUT PRESSURE" shown on Status Screen.	Input pressure is outside the specified limits (60 - 120psi).	Correct the pressure of the air or Nitrogen being supplied to the instrument. Check for proper connection of Air Hose to rear panel of the SupraVit Call MID Labs @ 1-800-929-5227
"HIGH INPUT PRESSURE" shown on the Status Screen.	System malfunction.	Call MID Labs @ 1-800-929-5227
"UNABLE TO CONTROL VACUUM" "VACUUM TRANSDUCER DISCREPANCY" "UNABLE TO RELIEVE VACUUM" shown on Status Screen.	System malfunction.	Call MID Labs @ 1-800-929-5227
"UNABLE TO ACHIEVE VACUUM" "EXTERNAL LEAK DETECTED" shown on Status Screen.	Collection Set improperly installed. Foreign matter present on aspiration drawer rear seal.	Open the aspiration drawer and check that the collection set is installed correctly. Clean the aspiration drawer rear seal per Section 6.6. If messages persist call MID Labs @ 1-800-929-5227
"FOOTPEDAL INTERLOCK FAILURE" shown on Status Screen.	Footpedal is slightly depressed during Aspiration Self Test. System malfunction.	Release footpedal and open and close aspiration drawer. Call MID Labs @ 1-800-929-5227
Reduced light output from Illuminator.	Bulb worn out. System malfunction.	Replace bulb. Call MID Labs @ 1-800-929-5227
Continuous sound of escaping air coming from inside console.	Input pressure is outside the specified limits (60 - 120 psi) At pressure above 120 psi a safety relief valve releases pressure. System malfunction.	Reduce input pressure to between 60 -120 psi Call MID Labs @ 1-800-929-5227
SupraBag® is overfilled.	SupraBag is filled beyond its capacity.	Replace SupraBag Collection Set.

5.1 SupraVit Troubleshooting Guide, continued

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Condition	Cause	Correction
Fluid is present at top of SupraBag®.	SupraBag is folded or constricted.	Place SupraVit instrument so that SupraBag hangs freely from drawer studs.
Vacuum seems to be reduced, but Actual Vacuum shown on Status Screen is correct.	Obstruction in handpiece or external tubing.	Determine cause of obstruction and correct.
	Many small bubbles in tubing between handpiece and console.	Determine source of air leak and correct.

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5.2 VitMate™ Troubleshooting Guide

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Condition	Cause	Correction
Displays not illuminated.	Instrument not connected to AC power.	Connect power cord from AC receptacle to Power Entry module on rear panel of the instrument.
	Blown fuse.	Replace fuse. Refer to Section 6.3, Fuse Replacement.
	System malfunction.	Call MID Labs @ 1-800-929-5227
Displays flash for 30 seconds or until a button is pressed after Power-On Self-Test completes.	Internal battery is dead.	Instrument will function but will use factory default settings. Battery is not user replaceable. Call MID Labs @ 1-800-929-5227
"Er" shown on CAUTERY POWER, U/S TIME, or ACTUAL PRESSURE display.	System malfunction.	Call MID Labs @ 1-800-929-5227
"CF" shown on CAUTERY POWER display.	Footpedal not connected.	Check connection between Cautery Footpedal and instrument.
CAUTERY does not work.	Power level too low.	Increase Cautery Power control.
	VitMate Cautery Footpedal not depressed.	Depress cautery footpedal and listen for high-frequency tone.
	Handpiece connections not secure.	Check Handpiece and connections to R-F OUTPUT connectors.
Cautery does not work using SupraVit Footpedal.	Cautery not enabled through SupraVit.	Push AUX button on SupraVit instrument and follow instructions for enabling Cautery Control.
"CC" shown on U/S TIME display.	No connection to vitrectomy system.	Check cable between ViteMate and vitrectomy system.
U/S TIME display is blank.	Handpiece not connected.	Check Handpiece and connection to U/S OUTPUT connector.
"HF" shown on U/S TIME display.	Handpiece fault.	Replace handpiece.

5.2 VitMate Troubleshooting Guide, continued

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Condition	Cause	Correction
U/S POWER bar-graph display does not become illuminated when vitrectomy system footpedal is depressed and swiveled to the right.	Interconnect wiring not secure.	Check cable between VitMate™ and vitrectomy system.
	Vitrectomy system not in "U/S" or "FRAG" mode.	Set vitrectomy system to Fragmentation mode.
	Vitrectomy system footpedal not in correct position.	Depress vitrectomy system footpedal and swivel footplate to right to activate ultrasound power. Listen for low-frequency tone.
Fragmentation does not work (bar-graph indicates correctly).	Handpiece needle loose.	Tighten handpiece needle with needle wrench.
	Handpiece and/or needle blocked.	Check handpiece and needle for blockage.
	Ultrasound power setting too low.	Increase ultrasound power by adjusting U/S Power control.
Fragmentation handpiece does not aspirate tissue correctly.	Aspiration vacuum setting on vitrectomy system too low.	Increase aspiration vacuum control on vitrectomy system.
	Kink in aspiration tubing.	Check tubing.
	Clogged handpiece or tubing.	Unclog by removing handpiece from eye and forcing sterile solution through aspiration tubing.
	Stopcock is in wrong position.	
Low Pressure Air System output seems low, but ACTUAL PRESSURE display is normal.	Leak between filter and eye.	Check for leaks, particularly at connections and stopcock.

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Section 6 Cleaning and Maintenance

This section of the manual provides information about the general cleaning of the instrument, cleaning the ultrasound handpiece, and fuse replacement.

6.1 General Cleaning

⚠ WARNING

Remove Power Cord from Power Entry Module before cleaning instrument.

When general cleaning is required, remove the power cord from the Power Entry Module. Clean the outside of the instrument by wiping it with a solution of mild detergent and water. Do not immerse the instrument in water. Avoid excessive amounts of cleaning solution around the front panel receptacles. Avoid using abrasive cleaners. Dry the instrument carefully before use.

6.2 Ultrasound Handpiece Cleaning and Sterilization

⚠ WARNING

Do not cold sterilize the ultrasound handpiece.

⚠ WARNING

The ultrasound handpiece must be cleaned after each surgical procedure to prevent the build up of contamination which could block flow through the ultrasound handpiece.

CAUTION

Allow ultrasound handpiece to cool for ten minutes after sterilization.

1. Remove the needle and tubing from the handpiece.
2. Flush the handpiece aspiration passage with warm distilled or de-ionized water. Repeat at least once.
3. Flush the handpiece with air to dry the internal fluid passages.
4. Sterilize using Gravity Displacement method for 10 minutes at 270° F with handpiece unwrapped.
5. Allow handpiece to cool for ten minutes after sterilization.

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6.3 Fuse Replacement

⚠ WARNING

Remove Power Cord from Power Entry Module before replacing fuse.

The fuse is located in one side of the Power Entry Module, on the rear panel.

Turn the Power switch to the Off position. Remove the power cord from the Power Entry Module.

To replace the fuse, pry the fuse module out of the Power Entry Module with a small screwdriver. Remove the old fuse from the fuse module, and replace it with an identical fuse.

SupraVit uses a 6 A, 250 V, 3AG or 5 X 20 mm fast blow fuse.

VitMate™ uses a 2.5 A, 250V, 3AG or 5 X 2 mm fast blow fuse.

Replace the fuse module in the Power Entry Module and press it in until it snaps shut.

Reconnect the power cord.

6.4 Illuminator Cleaning

To clean the illuminator front lens set:

1. Press the EJECT button to open the illuminator drawer.
2. Clean the flat surface of the front lenses using a sterile, dry cotton swab. Do not use any cleaning liquids or wetted material to clean lenses.

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6.5 Illuminator Lamp Replacement

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WARNING

THE LAMP BECOMES VERY HOT DURING OPERATION!

Severe burns could result from handling a hot lamp. Allow lamps to cool for ten minutes before replacing.

To replace an illuminator lamp:

1. Allow ten minutes for lamps to cool.
2. Press the EJECT button to cause the illuminator drawer to open.
3. Remove the Lamp Change Accessory from the spare lamp and slide it over the lamp to be replaced. Firmly grasp the silicon sleeve of the Lamp Change Accessory and remove the lamp by pulling straight up until it is out of the socket. Remove the lamp from the Lamp Change Accessory and discard.
4. Using the Lamp Change Accessory, remove the spare lamp from its holder. Be careful not to touch the lamp with your fingers; skin oil on the surface of the lamp will shorten lamp life. Insert the spare lamp in the lamp socket by aligning the lamp pins with the socket and gently pressing straight down. Ensure that both pins are fully seated in socket for correct lamp alignment.
5. Replace the spare lamp with a new lamp and slide the Lamp Change Accessory over it for safe storage. Use only lamp type BRL 12 Volts, 50 Watts. For maximum illumination MID Labs recommends use of Osram/Sylvania Lamp #54034 (Old Osram part number HLX64610).

6.6 Aspiration Drawer Rear Seal Cleaning

To clean the seal at the left rear of the aspiration drawer opening:

1. Turn the Power switch to the Off Position. Remove the power cord from the Power Entry Module.
2. Open the aspiration drawer by pulling on the handle.
3. Refer to Figure 5-1. Use a penlight to aid in locating the seal [1] which is at the left rear of the drawer opening, about 3 inches directly behind the rear check valve [2]. Inspect the face of the seal for foreign matter.

4. Clean the face of the seal and the surrounding area, using a long handled, non-fibrous swab moistened with isopropyl alcohol.

5. Check that no foreign matter remains after cleaning.

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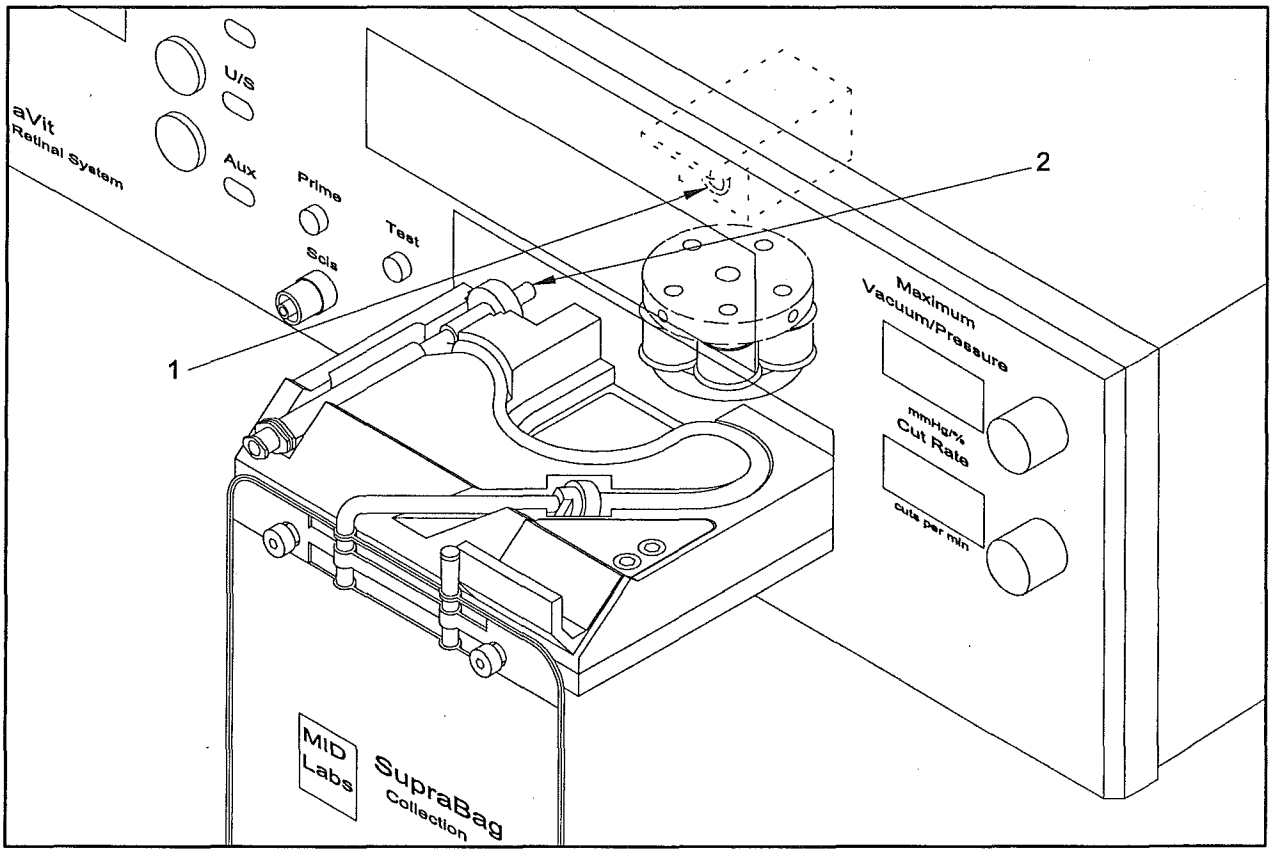

Figure 6-1

Aspiration Drawer Rear Seal

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Section 7 SupraVit Specifications

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This section of the manual contains the performance parameters that the instrument will meet under normal operating conditions. These specifications are subject to change without notice.

Manufacturer:	Medical Instrument Development Laboratories, Inc. 14477 Catalina Street San Leandro, CA 94577 Tel: 510-357-3952 1-800-929-5227 FAX: 510-357-1582
Intended Use:	Vitreoretinal procedures
Weight:	32.5 lbs (14.8 kg)
Dimensions:	19 in (48 cm) W x 5.8 in (14.7 cm) H x 15.4 in (39 cm) D
Electrical Power:	100–240 VAC, 50/60 Hz, single phase, 5.5A (Max.)
Pneumatic Power:	Compressed air or nitrogen @ 60–120 psi
Fuse Type:	6 A, 250 V, 3AG or 5 X 20 mm fast blow fuse
Aspiration:	0–500 mmHg, linear control
Vitreous Cutting:	Pneumatic, guillotine style 60–800 cpm
Fiber Optic Illumination:	Two independently adjustable outputs Color temperature unaffected by intensity adjustment
Scissors Drive:	Proportional or pulsed mode 60–200 cpm in pulsed mode 0–100% of 40 psi drive pressure
VitMate™ Interface:	Control signal operates VitMate™ ultrasound Control signal operates VitMate™ cautery
	Underwriters Laboratories Listing 88HJ, Medical Equipment

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Section 8 VitMate Specifications

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This section of the manual contains the performance parameters that the instrument will meet under normal operating conditions. These specifications are subject to change without notice.

Manufacturer:	Medical Instrument Development Laboratories, Inc. 14477 Catalina Street San Leandro, CA 94577 Tel: 510-357-3952 1-800-929-5227 FAX: 510-357-1582
Intended Use:	Vitreoretinal procedures, in conjunction with a MID Labs MVS®XII, MVS®XX, or SupraVit™; Storz MicroVit®; or Alcon® MVS®XII or MVS®XX vitrectomy system.
Weight:	13.5 lbs (6.13 kg)
Dimensions:	19 in (48.25 cm) W x 5.06 in (12.9 cm) H x 13 in (33.02 cm) D
Electrical Power:	100–240 VAC, 50/60 Hz, Single phase, 2.3A (Max.)
Fuse Type:	2.5 A, 250 V, 3AG or 5 X 20 mm fast blow fuse
Cautery Output:	600 kHz floating bipolar isolated 10 W maximum across 600 Ohm load Amplitude modulated
Ultrasound Output:	40 kHz, 20 W maximum, autotuned Continuous or pulsed power delivery selectable via front panel pushbutton Pulse rate fixed @ 10 pulses/second
Low Pressure Air	0–99 mmHg above atmospheric pressure Output: 1000 cc/minute minimum flow capability at 99 mmHg
Ultrasound Handpiece:	Piezoelectric, 0.48 in (1.22 cm) diameter x 4.27 in (10.8 cm) long, 20 ga. titanium needle Autoclavable, gravity displacement Underwriters Laboratories Listing 88HJ Medical Equipment

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Section 9 Limited Warranty

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9.1 Limited Warranty Terms

Medical Instrument Development Laboratories, Inc. (MID Labs) warrants that the SupraVit VRS 2000 System shall be free from defects in materials and workmanship for a period of two (2) years from date of installation at the purchaser's facility. Limited warranty extends to the original purchaser only.

MID Labs shall be relieved of all liabilities under this limited warranty if:

1. The product has been damaged during shipping or damaged by accident, abuse, misuse, modification, or misapplication.
2. The system was operated with any accessory, equipment, or part not specifically approved by MID Labs, or if the system was not used for the purpose intended.
3. The system was repaired or serviced by anyone other than MID Labs.
4. The system is not operated in accordance with MID Labs' instructions and specifications.
5. The buyer fails to report the defective item(s) to MID Labs within thirty (30) days of the discovery of the defect.

MID Labs' obligation under this limited warranty shall be the limited to the repair or replacement, at MID Labs' option, of any SupraVit VRS 2000 System that, upon MID Labs' inspection, is deemed defective. Transportation and insurance charges incurred in transporting this product to MID Labs are not covered by this warranty.

MID Labs' sole liability for any claim for loss or liability arising out of or in connection with the sale or use of any MID Labs product shall in all cases be limited to an amount equal to the purchase price of the products sold by MID Labs which resulted in the claim. In no event shall MID Labs be liable for any special, incidental, indirect, or consequential damages resulting from any defect, malfunction, or failure of this product.

THIS LIMITED WARRANTY IS EXCLUSIVE AND SHALL BE IN LIEU OF ALL OTHER EXPRESSED WARRANTIES, INCLUDING ANY WARRANTY OF FITNESS OR MERCHANTABILITY, AND WHETHER WRITTEN, VERBAL, OR IMPLIED AND THE PURCHASER WAIVES ALL OTHER WARRANTIES, GUARANTEES, OR LIABILITIES ARISING BY LAW OR OTHERWISE.

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9.2 How to obtain warranty service

You should immediately notify MID Labs of problems encountered during the warranty period. In any event, MID Labs must be notified of any problem no later than five (5) days after said warranty has expired. In order to obtain warranty service, a return authorization **must** be obtained from MID Labs prior to returning the unit for repair. The following information must accompany all returned units:

1. Your name, address, and telephone number
2. The return authorization number
3. List of equipment and quantity being returned
4. Lot or serial number
5. Invoice number
6. A description of the problem

Ship or otherwise return the product with transportation and insurance costs prepaid to:

Medical Instrument Development Laboratories, Inc.

14477 Catalina Street

San Leandro, CA 94577

Telephone 1-510-357-3952

1-800-929-5227 (Inside U.S.A. only)

FAX 1-510-357-1582

9.3 Return Policy

Authorization must be obtained from MID Labs prior to shipping equipment or accessories for return. Authorization does not assure that credit will be issued. In order to receive proper credit, returned goods must be shipped with transportation and insurance costs prepaid and must include:

1. List of equipment, disposables, and/or accessories for return
2. Lot and serial number
3. Return authorization number
4. Original invoice number
5. Reason for return

All returns are subject to a restocking charge.

In the event of a shipping error, MID Labs must be notified within ten (10) working days of receipt of goods.

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